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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte OLE THASTRUP, SARA PETERSEN BJORN, SOREN TULLIN, KASPER ALMHOLT, and KURT SCUDDER

Appeal 2010-007661
Application 10/072,036
Technology Center 1600

Before DEMETRA J. MILLS, LORA M. GREEN, and JEFFREY N. FREDMAN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 44-54, 73-80, and 82.[1] We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Claim 81 stands withdrawn from consideration (App. Br. 4).

STATEMENT OF THE CASE

Claim 44 is representative of the claims on appeal, and reads as follows:

44. A method for screening a library of compounds to detect a biologically active compound by detecting intracellular translocation of a subunit of a component of an intracellular pathway affecting intracellular processes, which subunit exhibits a biological activity of the component, comprising:

(a) culturing one or more cells containing a nucleotide sequence coding for a hybrid polypeptide comprising a luminophore linked to the subunit under conditions permitting expression of the nucleotide sequence,

(b) incubating the one or more cells with at least one compound of the library of compounds,

(c) screening the library of compounds to determine whether the at least one compound of the library of compounds has a biological function or biological effect on the subunit in the one or more cells, wherein translocation of the subunit in response to the at least one compound of the library of compounds determines that the at least one compound has a biological function or biological effect on the subunit, and

(d) measuring the light emitted from the luminophore in the incubated one or more cells and determining a variation with respect to the emitted light from said luminophore, such variation being indicative of the translocation of the subunit in said one or more cells and said translocation being indicative that said at least one compound of the library of compounds to be screened is biologically active with the component.

Claims 45 and 46 are the other independent claims on appeal. Claim 45 is also drawn to a method "for screening a library of compounds to detect a biologically active compound by detecting intracellular translocation of a subunit of a component of an intracellular pathway affecting intracellular processes, which subunit exhibits a biological activity of the component." And claim 46 is drawn to a method of "for screening a library of compounds to detect a biologically active compound by detecting intracellular

translocation of a subunit of a biologically active polypeptide affecting intracellular processes, which subunit exhibits a biological activity of the polypeptide."

The following grounds of rejection are before us for review:

I. Claims 44-52, 73, 77-80, and 82 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Htun[2] as evidenced by Carey[3] or Agarwal.[4]

II. Claims 44-52, 73-80, and 82 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of by Htun as evidenced by Carey, Agarwal, Sonenberg,[5] and Dunlay.[6]

III. Claims 53 and 54 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of by Htun as evidenced by Carey, Agarwal, Sonenberg, and Dunlay, as further combined with Cormack.[7]

IV. Claim 48 stands rejected under 35 U.S.C. § 112, first paragraph, as containing new matter.

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[2] Htun, et al., Visualization of glucocorticoid receptor translocation and intranuclear organization in living cells with a green fluorescent protein chimera, 93 PROC. NATL. ACAD. SCI. USA 4845-4850 (1996).
[3] Carey et al., Evidence Using a Green Fluorescent Protein-Glucocorticoid Receptor Chimera that the RAN/TC4 GTPase Mediates and Essential Function Independent of Nuclear Protein Import, 133 J. CELL BIOL. 985-996 (1996).
[4] M. K. Agarwal, The Antiglucocorticoid Action of Mifepristone, 70 PHARMACOL. THER. 183-213 (1996).
[5] Sonenberg et al., US 5,874,231, issued Feb. 23, 1999.
[6] Dunlay et al., US 5,989,835, issued Nov. 23, 1999.
[7] Cormack et al., FACS-optimized mutants of the green fluorescent protein (GFP), 173 GENE 33-38 (1996).

We reverse all of the above rejections.

ISSUES (Rejections I, II, and III)

Has the Examiner established by a preponderance of the evidence that Htun inherently teaches a subunit of a component of an intracellular pathway that affects an intracellular process, or that the subunit exhibits a biological activity of the component?

FINDINGS OF FACT

FF1 The Examiner's statement of the anticipation rejection over Htun may be found at pages 3-6 of the Answer.

FF2 Htun teaches that unliganded glucocorticoid receptor (GR) resides in the cytoplasm, and that hormone activation leads to nuclear accumulation and gene activation (Htun, p. 4845, first column).

FF3 The Examiner relies on Carey for teaching that the GR-GFP taught by Htun inherently binds to Ran (Ans. 4). Thus, according to the Examiner, "Ran/GR-GFP is a component of the glucocorticoid receptor signaling pathway, with Ran and GR-GFP being subunits of the component" (id.).

FF4 Specifically, Carey investigated the effects of different Ran mutants on nuclear transport of GR-GFP (Carey, p. 987, second column).

FF5 Carey specifically states that the "observed inhibition of GR-GFP translocation by Ran mutants is a direct effect on nuclear transport, rather than a long-term, indirect response" (id. at 990, second column).

FF6 The Examiner relies on Agarwal for teaching that GR inherently binds heat shock proteins (HSPs) in the cytoplasm (Ans. 4). The Examiner therefore finds that the "heat shock protein(s)/GR is a component of the

glucocorticoid receptor signaling pathway, with heat shock protein(s) and GR being subunits of the component" (id. at 5).

FF7 Specifically, Agarwal teaches that the binding of ligand to the steroid hormone receptor leads to dissociation of HSPs and other proteins (Agarwal, p. 197, Fig. 1 caption).

PRINCIPLES OF LAW

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). In general, a limitation is inherent if it is the "'natural result flowing from'" the explicit disclosure of the prior art. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999)(quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)).

ANALYSIS

The independent claims on appeal require "detecting intracellular translocation of a subunit of a component of an intracellular pathway affecting intracellular processes," wherein in claim 46 the component is a polypeptide. We note that both the Examiner and Appellants interpret that phrase as requiring direct binding of the subunit to another subunit, for example, direct binding of GR receptor to Ran or heat shock protein, to form a component, that is a complex of the subunits, such as the GR receptor/Ran complex or the GR receptor/HSPs complex. As that interpretation is reasonable in view of the teachings of the Specification, we also adopt it.

Appellants argue that none of the data or discussions of Carey states that Ran binds the GR protein (App. Br. 11). Appellants further argue that while the Examiner relies on Agarwal for teaching that the GR protein inherently binds heat shock proteins (HSPs), Agarwal does not teach that the GR protein "exhibits the biological activity" of the purported HSP/GR complex, nor that "the HSP/GR complex translocates as a 'component of an intracellular pathway'" (id. at 12).

We agree with Appellants that the Examiner has not established a prima facie case of anticipation. First, while Carey teaches that "inhibition of GR-GFP translocation by Ran mutants is a direct effect on nuclear transport, rather than a long-term, indirect response" (FF5), the ordinary artisan would interpret that statement as that while there is a possibility that Ran binds directly to the GR receptor, it may also exert its influence in other ways.

As to Agarwal, while Agarwal does teach that HSPs form an association with the unliganded receptor, Agarwal teaches that upon binding of the steroid ligand, the HSPs dissociate from the receptor. The Examiner thus does not explain how the GR receptor subunit has the same biological activity of the GR receptor/HSPs complex.

CONCLUSIONS OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that Htun inherently teaches a subunit of a component of an intracellular pathway that affects an intracellular process, or that the subunit exhibits a biological activity of the component. We are thus compelled to reverse the rejection of claims 44-52, 73, 77-80, and 82 under 35 U.S.C. § 102(b) as being anticipated by Htun as evidenced by Carey or Agarwal.

In addition, as none of Sonenberg, Dunlay, or Cormack are relied upon to remedy those deficiencies of Htun, we also reverse the rejection of claims 44-52, 73-80, and 82 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of by Htun as evidenced by Carey, Agarwal, Sonenberg, and Dunlay, as well as the rejection of claims 53 and 54 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of by Htun as evidenced by Carey, Agarwal, Sonenberg, and Dunlay, as further combined with Cormack.

ISSUE (Rejection IV)

Has the Examiner established by a preponderance of the evidence that the recitation of "synthetic chemical compound" in claim 48 constitutes new matter?

FINDINGS OF FACT

FF8 The Examiner's statement of the rejection may be found at pages 12-13 of the Answer.

FF9 Specifically, Examiner finds that "[a] review of the [S]pecification does not reveal any support for 'synthetic chemical compounds' as a narrowing limitation of the library of compounds recited in the base claim" (Ans. 13).

FF10 The Examiner further finds that "a search of the specification does not reveal use of the word 'synthetic'" (id.).

FF11 The Examiner also finds that the term "synthetic compounds" is broader than the teaching of synthesizing organic compounds as taught in ¶118 of the Specification, as the term includes inorganic compounds (id. at 20).

PRINCILES OF LAW

The disclosure as originally filed need not provide "in haec verba support for the claimed subject matter at issue," rather, the disclosure should convey to one skilled in the art that the inventor was had possession of the invention at the time of filing. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citations omitted).

ANALYSIS

Appellants argue:

> A compound is a synthetic chemical compound when the compound is prepared by chemical synthesis. The specification teaches that the compounds to be screened are a "compound or mixture of compounds prepared by organic synthesis" (paragraph [0118]), "chemical substances" (paragraphs [0012 and 0026]), and "chemical compounds" (paragraph [0124]). Taken together, these disclosures provide adequate written description for the screening of a "synthetic chemical compound."

(App. Br. 19.)

We agree with Appellants, and conclude that the skilled artisan would understand that the inventors had possession of the subject matter of claim 48 at the time of filing.

CONCLUSION OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that the recitation of "synthetic chemical compound" in claim 48 constitutes new matter. We thus reverse the rejection of claim 48 rejected under 35 U.S.C. § 112, first paragraph, as containing new matter.

REVERSED

cdc